



Exploration Laboratory Analysis

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M. Krihak,¹ G. Perusek,² P. Fung³ and T. Shaw³

¹University of California Santa Cruz, NASA Ames Research Center, Moffett Field, CA

²NASA Glenn Research Center, Cleveland, OH

³NASA Ames Research Center, Moffett Field, CA

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Overview



Exploration Laboratory Analysis (ELA)

FY12 Highlights

- Functional Requirements – High Priority Analytes
- Documentation:
 - Level I Functional Requirements
 - Operational Concept
- Selection and head-to-head competition of in-flight laboratory analysis (IFLA) instrumentation
- Small Business Innovative Research (SBIR) Projects
- *Strengthened collaboration with Human Health and Countermeasures (HHC)*



ExMC Risk and Gap



Exploration Laboratory Analysis (ELA) project supports:

Exploration Medical Capability (ExMC) risk –

- *Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities*

Derived ExMC Gap 4.05 –

- *Lack of minimally invasive in-flight laboratory capabilities with limited consumables required for diagnosing identified Exploration Medical Conditions.*



Functional Requirements



Gap to Requirements

ExMC Gap
4.05

SMEMCL

Diagnosis

Treatment

ELA
Functional
Requirements

SMEMCL – Space Medicine Exploration
Medical Conditions List



HIGH PRIORITY ANALYTES



Functional Requirements



HIGH PRIORITY ANALYTES*

Operational Requirements

Basic Metabolic Panel	Hematology	Liver/ Renal Panel	Urinalysis
Glucose Sodium Potassium Creatinine	WBC Count Hgb Neutrophils Lymphocytes	AST ALT	Leukocytes Proteins Blood

*Under review



Functional Requirements



HIGH PRIORITY ANALYTES*

Research Requirements

Bone	Cardio & Muscle	Immune	Oxidative Stress	Hormones	Other
Ca ²⁺ NTx Creatinine (urine mg/dL) CTx OC GPx BSAP OPG RANKL sRANKL OP Vitamin D	cTn CK-MM hsCRP BNP ANP B2M Helical Peptide Homocysteine MMA Myostatin	TNF α IL1 β ILK-4 IL-6 IL-8 IL-10 TGFB NF-kB IFN gamma Neopterin	NOS SOD TRX	Norepinephrine Epinephrine Cortisol Testosterone Estradiol PTH PGF2A Angiotensin II Aldosterone Renin Total Plasma Proteins	Na ⁺ K ⁺ HgA1c K ⁺ Ca ²⁺ Na ⁺

*Under review



ELA Operational Concept and Level I Functional Requirements



ELA Operational Concept



Purpose

The operations concept:

- (i) Constitutes the ELA portion of the ExMC Element Operation Concept Document
- (ii) Provides the operational scenarios that will form basis for ELA system requirements

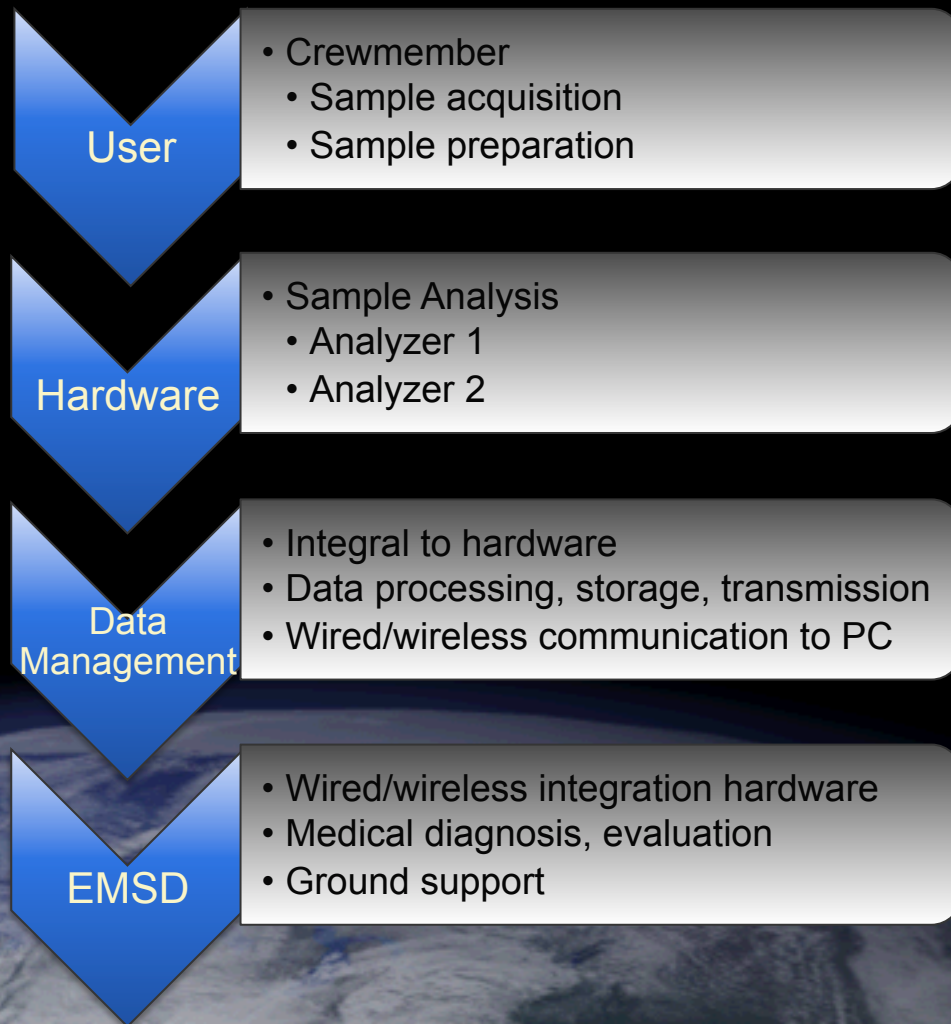
The ELA operational concept was presented and reviewed at the ExMC (Systems Requirements Review) SRR2 in August 2012



ELA Operational Concept



ELA System Configuration





Level I Functional Requirements



Exploration Laboratory Analysis (ELA) Project - Purpose

- Defines top-level operational requirements for the ELA project with respect to the Exploration Medical System (EMS).
 - For ExMC, Level I functional requirements support the:
 - Deep space exploration
 - For research, requirements for the intended HHC studies on ISS.
- Facilitate the diagnostics of several medical conditions.
- Track the development of hardware by the Human Research Program (HRP) elements, the National Space Biomedical Research Institute (NSBRI), and Small Business Innovation Research (SBIR) projects.



Level I Functional Requirements



Exploration Laboratory Analysis (ELA) Project – Scope

- Defines requirements for clinical laboratory analysis equipment intended to:
 - Support medical operations based on Level IV standard of care (NASA-STD-3001)
 - Medical conditions outlined in the SMEMCL for a Near-Earth Asteroid (NEA) mission.
 - Address research needs that will accommodate a variety of biological specimens and provide a wide range of analytical capabilities
- Hardware selection will be based on:
 - Assessment of commercial-off-the-shelf (COTS) instrumentation
 - Evaluation of performers in the IFLA competition



IFLA Assays and Competition



IFLA Assays and Competition



- Follow-on to the Defense Venture Catalyst Initiative (DeVenCI)
- Four companies down-selected to participate in a run-off competition
 - DNA Medicine Institute (Phase III SBIR), Nanomix, OPKO (Claros), Rice Univ.
 - Joint-effort between HHC and ExMC
- Goal is develop and demonstrate four assays by April 30, 2013
 - NTx
 - IFN- γ
 - TNF- α
 - (25-OH) Vitamin D
- Competition will culminate with a demonstration at JSC
 - On-site analysis of 15 blind samples



Small Business Innovative Research (SBIR)



Small Business Innovative Research



Phase I solicitation: X13.01 Smart Phone Driven Blood-Based Diagnostics

- Two performers completed Phase I contracts.
- A single Phase II performer, Intelligent Optical Systems, has been recommended for selection as Required to meet HRP Objectives (award pending funding appropriations).
- Phase II will seek to demonstrate at least two of the medical operations panels that are shown below:
 - Basic metabolic panel (Chem8)
 - Blood gas panel (PaO₂, PaCO₂, SaO₂, HCO₃, pH)
 - Cardiac panel (troponin I, CK-MB)
 - Liver/renal (total bilirubin, direct bilirubin, ALP, ALT, AST) panel



Future Work



Exploration Laboratory Analysis FY13

- Develop technology downselect plans for:
 - HHC run-off competition
 - ExMC ELA under the EMSD
- Develop ELA technology development plan for ExMC
- Manage the SBIR Phase II performance
- Market survey update